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BROAD AGENCY ANNOUNCEMENT

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U.S. Army Medical Research and Materiel Command
BAA 04-1

PREFACE

The U.S. Army Medical Research and Materiel Command's (USAMRMC) mission is to provide solutions to medical problems of importance to the American warfighter at home and abroad. The scope of this effort and the priorities attached to specific projects are influenced by changes in military and civilian medical science and technology, operational requirements, military threat assessments, and national defense strategies. The extramural research and development program plays a vital role in the fulfillment of the objectives established by the Command. General information on USAMRMC can be obtained from the USAMRMC website (https://mrmc.detrick.army.mil/).

This Broad Agency Announcement (BAA) is intended to solicit research ideas, and is issued under the provisions of the Competition in Contracting Act of 1984 (Public Law 98-369), as implemented in the Federal Acquisition Regulations. This Announcement provides a general description of the Command's research programs, including specific areas of interest; general information; the evaluation and selection criteria; and proposal preparation instructions. The Appendices include forms that are required with the submission of a full proposal. Research proposals are sought from educational institutions, nonprofit organizations and private industry. **This is a continuously open announcement; preproposals may be submitted and will be evaluated at any time throughout the year, unless timeframes are stated in a separate announcement.**

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is continuing the process of preparing this BAA for electronic commerce. The BAA will be revised as other electronic processes are developed. Amendments of this brochure will be advertised on the USAMRAA website (www.usamraa.army.mil) and in the Fedbizopps (http://www.fedbizopps.gov/). Many of the programs and areas of interest may not have funding readily available, but the status of funds will be part of the advice elicited from a proposal. From time to time separate announcements or calls for proposals may supplement this BAA. These supplements will be featured on our homepage.

Questions concerning the preparation of preproposals or proposals can be emailed to (QA.BAA@DET.AMEDD.ARMY.MIL) or faxed (301-619-6662) to Cheryl Miles at USAMRAA. Telephonic inquiries can be answered by calling 301-619-7148.

Mail: U.S. Army Medical Research Acquisition Activity
ATTN: BAA 04-1
820 Chandler Street
Fort Detrick, MD 21702-5014

BAA Preproposal Form (http://www.usamraa.army.mil/pages/tatrc/02baapre.cfm)

BAA Conference Form (http://www.usamraa.army.mil/pages/tatrc/02conf.cfm)

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I. RESEARCH AREAS OF INTEREST

A. MILITARY INFECTIOUS DISEASES RESEARCH PROGRAM

Research on naturally occurring infectious diseases emphasizes the prevention, diagnosis and treatment of endemic diseases with demonstrated or potential capability to seriously diminish military operational effectiveness. Diseases of principal interest in this program are: malaria, infectious bacterial diarrhea and dengue. Other areas of interest include vector control, hemorrhagic fever viruses (particularly hantaviruses), meningococcal group B infection, scrub typhus and leishmaniasis.

1. Research and Development of Preventive Measures for Infectious Diseases includes:

a. Vaccines. Studies to characterize infectious agents, define human protective immune responses and select candidate immunogens and methods of delivery for vaccine development. Studies of pathogenesis and preclinical vaccine testing may use animal models. Candidate field sites for evaluating vaccine efficacy in humans are solicited.

b. Antimalarial Drugs. Studies applicable to the discovery, design, and development of prophylactic drugs for malaria to include drug design, synthesis, screening, mode of action, and mechanisms of drug resistance. Topics of interest include investigations of parasite metabolism and structural biology to identify potential molecular targets for therapy, to include proposals which complement and exploit the malaria genome sequencing effort.

c. Diagnosis. Studies include the development of field-deployable, common diagnostic systems, including immunologically-based and nuclieic-acid-based platforms for detection, surveillance and diagnosis of naturally occurring infectious agents of military importance. Studies also include improvement of specimen processing techniques for a variety of clinical specimens that are compatible with the diagnostic systems currently under development within the DoD.

d. Vector Control. Studies on arthropod vectors and vector-borne diseases, with primary emphasis on malaria, dengue and typhus. Studies include research on vector-pathogen-human interaction, improvement of means for risk assessment (identification and classification of vectors, improved surveillance techniques, rapid assays for pathogens in vectors) and improvement of vector control and personal protection techniques applicable to protecting military forces in the field.

e. Disease distribution and epidemiology. Studies to research foreign infectious disease distribution for militarily significant diseases. Studies include procurement of country-specific disease statistics and/or surveillance data and research to develop methodologies to estimate disease risk in the absence of country-specific public health data. These studies shall incorporate current GIS-based technologies to produce geospatially referenced data sets and distribution maps. Studies also include procurement of country-specific epidemiologic data, pathogens and clinical specimens to map molecular epidemiology of key pathogens.

2. Research and Development of Therapeutic Measures for Infectious Diseases includes studies to synthesize, screen, and develop therapeutic drugs for malaria and other military relevant infectious agents. Therapeutic drug development is secondary to the prophylactic development program [see 1b, above], which receives program emphasis. However, proposals dealing with novel drug delivery systems, i.e., sustained release and methods of targeting drugs to reduce toxicity or delivery of drugs of clinical importance to the active sites, are of interest.

B. COMBAT CASUALTY CARE RESEARCH PROGRAM

The Combat Casualty Care Research Program provides integrated capabilities for far-forward medical care to reduce the mortality and morbidity associated with major battlefield wounds and injuries. A primary emphasis of the Research Program is on the identification and development of medical techniques and materiel (medical devices, drugs, and biologics) for early intervention in life-threatening battle injuries. Because battlefield conditions impose severe constraints on available manpower, equipment and medical supplies available for casualty care, we place a premium on medical interventions that can be used within the battle area or as close to it as possible, before or during medical evacuation. We prefer medical techniques and materiel that can be used by first responders, which means that medical materiel must be easily transportable, i.e. small, lightweight, and durable in extreme environments and handling; devices must be easy to use, low maintenance, with self-contained power sources as necessary. Drugs and biologics, ideally, should not require refrigeration or other special handling. Materiel and techniques must be simple and rapid to employ. Research efforts are needed in principles and technology available to enhance self- and buddy-aid; techniques, methods, or materials to improve basic and advanced life support for severely injured persons; monitoring, and sustainment of severely injured casualties during episodes of delayed or protracted evacuation; management of patients when treatment is delayed as a result of temporary overloading of battlefield facilities; and enhanced capability for triage of large numbers of casualties and staged treatment in the field. We are interested in existing materiel for which concept and/or patient care efficacy have already been demonstrated, but require improvement to meet our military constraints.

The following paragraphs describe objectives of particular interest:

The principal cause of death among soldiers who die within the first hour of wounding is hemorrhage. As a consequence, the Combat Casualty Care Research Program strongly supports research and development of technologies to stop blood loss, to resuscitate the casualty, and to limit the immediate, short- and long-term deleterious consequences of severe hemorrhage. Included in this area of interest are noninvasive or minimally invasive sensors to detect and warn of impending vascular collapse and/or significant tissue damage due to perfusion deficits. Examples of specific products include: local and systemic hemostatic agents, treatments to enhance oxygen delivery and perfusion of tissue, equipment and procedures for effective fluid resuscitation of casualties, and enhanced resuscitation fluids. Also of interest is the improved preservation, storage, transportability, and processing of red blood cells, platelets and plasma.

Secondary damage to organs frequently occurs after trauma. We are interested in materiel that can reduce acute secondary damage such as ischemia/reperfusion injury, cell death, general organ failure, and secondary brain/spinal cord damage. This objective includes methods to reduce cellular demand for oxygen and metabolic substrates.

The Combat Casualty Care Research Program supports additional aspects of casualty care. These include drugs or devices to protect and stabilize hard and soft tissue wounds and to mitigate secondary tissue damage and death, and the treatment and prevention of dental injury or disease in austere environments. We are interested in non-invasive sensors, algorithms, processors, simulation, modeling and physiology databases for remote triage, monitoring and management of casualties; and products to maintain casualties during prolonged evacuation.

C. MILITARY OPERATIONAL MEDICINE RESEARCH PROGRAM

Operational medicine research centers on the protection of health and sustainment of military performance in the face of stressors that confront soldiers in a deployment. Research is directed to protect and enhance soldiers in a deployment. Research is directed to an improved understanding of the physiology of the deployed soldier, the development of improved damage risk criteria to protect against materiel and environmental hazards, and development of specifications, algorithms and models for strategies and interventions to protect health and performance. This research program is closely coordinated with programs funded by the Office of Naval Research in the area of Military Operational Medicine research. The Army Research Office also supports extramural basic research for this program in a coordinated effort on Enhancing Soldier Performance.

Current areas of emphasis include:

1. Environmental physiology and metabolic interventions such as thermal physiology and injury prevention, nonfreezing cold injury protection, sustainment in mountainous terrain, metabolic regulators to optimize performance in adverse environments, nutritional optimization of soldier mental status, optimization of physical performance and musculoskeletal injury prevention.

2. Biodynamics and injury sciences research such as blunt trauma models, soldier performance and injury-based criteria and crash injury protection; laser eye injury protection and treatment.

3. Neurobehavior and toxicology research such as deployment exposure assessment systems for environmental contaminants, rapid assessment methods for drinking water safety, combined toxic gas models, stress diagnostic methods, deployment stress factors, sleep/wake performance optimization and performance consequences, and military health behaviors promotion and interventions.

Funding opportunities are limited to extramural performers conducting research, which directly augments the current research program objectives and usually involves close coordination with and/or direct support of the intramural performing laboratories.

D. MEDICAL BIOLOGICAL DEFENSE RESEARCH PROGRAM

The Medical Biological Defense Research Program provides medical countermeasures for biological warfare agents. These countermeasures include specialized medical materiel or procedures designed to enhance protection. The priorities of the program are a) prophylaxis or pretreatment to prevent any casualty, b) identification and diagnosis of biological agents, and c) treatment or supportive care regimens.

Examples of some of the infectious agents of interest are those causing anthrax, plague, glanders; the Ebola, Marburg, Venezuelan, western and eastern equine encephalitis viruses; and poxvirus models of variola virus. Examples of toxins of interest include those from plants (ricin), bacteria (Staphylococcal enterotoxins, botulinum) and membrane damaging toxins and venoms from snakes, snails and insects.

The following are the overarching research and development goals:

1. Viral, Toxin and Bacterial Studies.

a. Identification and characterization of organisms and toxins. Molecular antigenic analysis; development of diagnostic assays; studies on structure and function that are related to mechanism of action, binding, internalization and interaction with the immune system and neutralizing antibodies; investigation of pathogenesis and immunology that will allow decision regarding the optimal approach to disease prevention and control. Specific long-term goals include development of physiological support methodologies, diagnostic tests, rational prevention and control strategies, and improvement of existing products.

b. Vaccine development, with emphasis on protection from agents in aerosol exposure, molecular approaches for development of vaccines, measurement of relevant cellular and humoral protective immune responses, and expression or production of protective antigens using recombinant technology. Development of vaccines for specific toxins and disease agents involving the generation, selection and characterization of attenuated strains or inactivated purified antigen preparations, to include polyvalent vaccines that are more broadly effective. Safer means of passive immunization such as production of human monoclonal or modified antibodies that are despeciated are also of interest. Identification of surrogate markers of protection for the agents identified above and development of assays to assess such protection are needed.

c. Development of improved methods for delivery of vaccines, including adjuvants, nucleic acid vaccines, methods for oral or nasal immunization with inactivated, live and subunit antigens; sustained release formulations; and methods for delivery of antigens for specific induction of mucosal immunity and development of methods to enhance appropriate immune responses to include co-delivery of cytokines.

d. Preparation of research quantities of highly purified and characterized toxins as well as studies on basic chemistry, mechanisms of action, metabolism and excretion.

2. Drug Development. Development, synthesis and testing of compounds that possess antiviral, antibacterial, immunomodulatory or antitoxin activities, with emphasis on compounds that provide broad, nonspecific protection against viruses, bacteria and toxins described above. Studies of their pharmacokinetics and other measurements relevant to more effective drug use are also of interest. Development of lead compound(s) that are potent, active-site inhibitors that may include combinatorial-derived organic molecules and/or rationally designed transition-state substrate analogs. Testing for potency is required. Approaches that will be considered include but are not limited to computational chemistry, combinatorial organic synthesis, high throughput *in vitro* screening and X-ray analysis of ligand-toxin co-crystals.

a. Discovery of novel or unique biochemical elements or compounds with antiviral, antibacterial or antitoxin activity against the listed organisms.

b. Development of testing models for evaluation of compounds effective against toxins of several classes, including pre- and post-synaptic toxins, membrane-damaging toxins, toxins which inhibit protein synthesis and others.

c. Mechanism of action studies of immunomodulators, including characterization of effector cells (lymphocytes, macrophages) effector mechanisms, ancillary effects on other cells of the immune system and production and characterization of cytokines released as a consequence of immunomodulation.

3. Identification and Diagnosis. The investigation and evaluation of sensitive and specific methods of identifying and diagnosing for both antigens and antibodies of viruses, bacteria and rickettsia in biological materials. Development of sensitive and specific immunologic, chemical or biological assays for the rapid (within minutes) and reliable diagnoses of (a) acute diseases due to agents of potential biological threat, (b) the identification of toxins or their metabolites in biological samples. Assay may include antigen, antibody or metabolite detection or the use of nucleic acid probes or synthetic antigens. In addition, there is interest in the development of rapid identification and diagnostic methods for the assay of toxins, metabolites and analogs in clinical specimens.

E. MEDICAL CHEMICAL DEFENSE RESEARCH PROGRAM

The Medical Chemical Defense Research Program seeks to preserve combat effectiveness by timely provision of medical countermeasures in response to Joint Service chemical warfare defense requirements. The fundamental orientation of the program is to protect U.S. forces from the effects of chemical warfare agents by developing protective, pretreatment, and prophylactic products, providing products usable by the individual soldier for immediate treatment of chemical warfare agent exposures, developing antidotes/therapeutics to chemical warfare agents, defining care procedures for chemical warfare agent casualties, and advancing management of these casualties. The medical countermeasures are intended to preserve and sustain the soldiers' combat effectiveness in the face of combined threats from chemical and conventional munitions on the integrated battlefield.

The broad goals of this program are:

1. Maintain the Technologic Capability to meet present requirements and counter future chemical warfare agent threats. The program will maintain the scientific base and technological capability to develop timely medical countermeasures for both current and future chemical warfare agent threats. Research funded by this program will be used to identify concepts and candidate medical countermeasures for use by the individual soldier or by medical personnel. Basic and applied research are both supported, and may address topics as diverse as determining sites/mechanisms of action and effects of exposure to chemical warfare agents with emphasis on exploitation of neuroscience technology, respiratory, ocular, and dermal pathophysiology; identifying sites and biochemical mechanisms of action of medical countermeasures; exploiting molecular biological and biotechnological approaches for development of new approaches for medical countermeasures to chemical warfare agents; and exploiting molecular modeling and quantitative structure-activity relationships in support of drug discovery and design.

2. Provide Medical Countermeasures for the individual soldier to maintain combat effectiveness and prevent or reduce injury from chemical warfare agents. This goal encompasses research supporting development of new concepts for prophylaxes, pretreatments, antidotes, and therapeutic countermeasures; development of skin protectants and decontaminants; identification of factors which influence safety and efficacy of candidate medical countermeasures; and development and maintenance of preformulation, formulation, and radiolabeling capabilities.

3. Provide Medical Management of Chemical Casualties to enhance survival and expedite the return-to-duty of chemical warfare agent casualties through definitive therapies and life support technologies. This goal includes: developing concepts and therapeutic regimens and procedures for the management of chemical warfare agent casualties; developing diagnostic and prognostic indicators for chemical warfare agent casualties; and developing life-support equipment for definitive care of chemical warfare agent casualties.

Recent changes in the security situation facing the United States have not materially reduced the threat that chemical weapons present to American forces in the field. Many third world countries and terrorist groups have the capability of producing and delivering chemical warfare agents thus posing a substantial and serious threat to the armed forces of the United States.

Classical chemical agent threat categories include vesicant or blister agents (e.g., sulfur mustard), blood agents (e.g., cyanide), respiratory agents (e.g., phosgene) and nerve agents (e.g. GA or Tabun, GB or Sarin, GD or Soman, and VX).

Examples of pertinent research topics and areas currently of interest are:

a. Characterizing the mechanisms of vesicant agent pathophysiology to identify medical countermeasures against vesicant agents.

b. Developing innovative models of the pathophysiology of vesicant agent injury.

c. Identifying, synthesizing, and/or evaluating innovative candidate medical countermeasures against vesicant agents.

d. Identifying, exploring, and developing innovative clinical diagnostic, prognostic, and management approaches to vesicant agent casualties.

e. Characterizing the ocular lesions associated with vesicant agent exposures; developing treatments to ameliorate these injuries.

f. Characterizing the mechanisms of nerve agent-induced seizures and resulting pathophysiology; to identify medical countermeasures against nerve agent-induced seizures.

g. Identifying, synthesizing, and/or evaluating innovative candidate medical countermeasures against nerve agent-induced seizures.

h. Developing innovative models of the pathophysiology of nerve agent induced seizures.

i. Developing catalytic and/or stoichiometric chemical warfare agent scavengers from biological molecules (e.g., antibodies and enzymes) which provide protection against nerve agent incapacitation and lethality for extended periods following their administration.

j. Developing innovative models for evaluation of chemical warfare agent scavengers.

k. Identifying, expressing, synthesizing, and/or evaluating biotechnologically-derived or pharmaceutically-based scavengers as candidate medical countermeasures against chemical warfare agents.

l. Developing and evaluating custom-synthesized pharmaceuticals based on a detailed understanding of the pathophysiology and mechanisms of action of the chemical warfare agent structure and the function of the intended target molecule.

m. Developing catalytic and/or stoichiometric additives for use in skin protectants, or decontaminants, to protect against chemical warfare agents, especially vesicant and nerve agents.

n. Developing innovative models for evaluation of catalytic and/or stoichiometric additives in skin protectants or decontaminants.

o. Developing candidate formulations for skin protectants or decontaminants containing catalytic and/or stoichiometric additives and evaluating these formulations against chemical warfare agents.

p. Characterizing the pathophysiology and natural progression of chemical warfare agent-induced damage to human tissues.

q. Developing and validating innovative techniques for rapid and accurate analysis of human tissues and body fluids for detection of chemical warfare agent exposures.

r. Characterizing the effects of long-term or chronic exposures to chemical warfare agents and/or medical countermeasures to these agents.

s. Identifying, exploring, and developing innovative clinical diagnostic, prognostic and management approaches to nerve agent casualties.

t. Developing and validating field usable procedures for diagnosis, prognosis, and treatment of chemical warfare agent casualties under both field and laboratory conditions.

F. TELEMEDICINE AND ADVANCED TECHNOLOGY PROGRAM

The scope of the USAMRMC's telemedicine program includes identification, exploration and demonstration of key technologies and enabling biomedical principles required to overcome technological barriers that are both medically and militarily unique. The goals of this effort are to: 1) reduce the medical "footprint" and increase medical mobility while ensuring access to essential medical expertise and support; 2) incorporate health awareness into battlespace awareness; 3) improve the skills and efficiency of care providers; and 4) improve the delivery and quality of medical/surgical care throughout the battlespace.

Achieving the goals of telemedicine will require new technologies and the application of existing technologies to uniquely military health-related problems, as well as integration with other DOD modernization initiatives in the areas of information systems, telecommunications networks and logistics systems.

Research and development is required to enhance the following operational capability elements:

1. Joint Telemedicine-Joint Readiness: Joint Readiness is operational capability to use distributed medical databases, computer supported collaborative planning, dynamic modeling, surgical simulations, haptic feedback supported virtual reality and telesurgical robotics to enhance the combat trauma training of physicians, medical corpsmen, other healthcare providers, medical teams and units, and to improve the medical readiness of all personnel assigned to the joint warfighting force prior to deployment. This operational capability is supported by three operational capability elements: Individual Medical Skills and Proficiency, Unit Medical Skills Proficiency, and Information Superiority for Medical Applications.

a. Individual Medical Skills and Proficiency is defined as the ability to use advanced medical simulations to improve the training of Joint Service battlefield healthcare providers and ensure the currency of their individual and unit related combat medical skills. At the unit level, realistic simulations using stochastic modeling systems are needed for contingency operation medical mission planning, rehearsal and dynamic mission retasking. These systems will have embedded, fault tolerant, object oriented, dynamic scenario generation capabilities, and will be deployable, scaleable, and evolvable as mission requirements change.

b. Unit Medical Skills Proficiency is defined as the ability to provide home station training for distributed forces (active and reserve) using advanced live, linked and constructive collaborative simulations that represent joint medical task forces in realistic scenarios. Medical training systems will require sophisticated distributed, synchronized resident databases capable of automatic update and reconstruction, multilevel security with high rate, high bandwidth telecommunications support, and advanced collaboration planning capability.

c. Information Superiority for Medical Applications is defined as the ability to provide near real time information on individual and unit medical readiness of the Joint Task Force personnel prior to deployment. These systems will use intelligent agents to retrieve, filter and deconflict medical information contained in computerized medical records in large distributed medical databases, and apply artificial intelligence based analytical capabilities to

proactively project health parameters and appropriate medical interventions for Joint Forces prior to deployment. These systems will also include interactive, dynamic environmental effects and human systems performance modeling capabilities to forecast the near, mid and long term medical impacts of operational and resource decisions on the health status of the Joint Force.

2. Joint Telemedicine-Battlespace Medical Awareness: Battlespace medical awareness is the operational capability to acquire real time information about the position, status and movement of supported military personnel. Battlespace awareness provides commanders with medical situational awareness and display systems to rapidly acquire medically relevant information to precisely process and direct multimedia medical data to the appropriate user, and maintain the integrity of the processed information to provide a common view of the medical battlespace at different echelons and operational levels. Battlespace awareness is supported by functional capabilities for Medical Information Acquisition, Medical Data Fusion and Distribution, and Medical Situational Interfaces.

a. Medical Information Acquisition is defined as the ability to rapidly acquire a full spectrum of multimedia clinical and operational information. This information will enable commanders and medical providers to rapidly diagnose and treat casualties, to track soldiers and casualties during evacuation and to collect other assessment and reporting information on individual and unit casualties, activities, plans, and intentions. This capability element will ensure that commanders have dominant battlespace knowledge of their human resources. Novel user interfaces, such as those that employ voice interaction or natural language processing (NLP) are of interest. Other candidate technologies include, but are not limited to, mobile and wireless devices.

b. Medical Data Fusion and Distribution is defined as the capability to dynamically access large scale, distributed medical databases, and then integrate, process and direct multimedia medical information to appropriate users to support enhanced diagnosis, treatment and medical management of personnel within the joint battlespace. Information assurance and security is a high priority. Medical Data Fusion will include multi-echelon, real time monitoring capabilities to detect operations within the integrated combat healthcare delivery network, display deviations from plans, and rapidly recommend alternative courses of action.

c. Medical Situational Interfaces is defined as the ability to adjust the level and display of clinical, geospatial, operational and tactical situations, and tailor the presentation of information to accelerate and simplify the cognitive understanding of integrated information. Specifically, consistent battlespace understanding will integrate complex medical and tactical information with geospatial coordinates and advanced “smart” display presentations to provide commanders with a real time understanding of the medical implications of the joint operational battlespace. This information will be displayed in a manner that is congruent with the individual needs of operational commanders and the supporting medical personnel. Medical displays also encompass the use of individual displays that assist healthcare providers in the treatment of casualties.

3. Joint Telemedicine-Effective Employment of Medical Forces: Effective Employment of Medical Forces is the operational capability to more effectively and efficiently employs medical assets within the battlespace. It is dependent upon three functional capabilities, prognostics and planning, telemedical management of medical forces and execution of time-critical medical missions. These capabilities allow the commander to better monitor and project the health of the force, locate, diagnose and treat individual casualties, tailor joint medical forces to the needs of specific missions and regulate the flow of casualties throughout the battlespace. It allows commanders to dynamically integrate tactical and supporting medical assets throughout

the theater and the CONUS supporting base to better coordinate health care delivery. Effective employment of medical forces is supported by functional capabilities for medical force management and improved evacuation and treatment.

a. Medical Force Management is defined as the ability to reduce the medical footprint by using superior medical situational awareness, advanced diagnostics, communications and information technology to more effectively manage the care of friendly forces through the dynamic synchronization of medical resources in both the Theater of Operations and the CONUS sustaining base. This capability includes multi-echelon, real-time monitoring capabilities to detect operations within the integrated combat health care delivery network, display deviations from plans, and rapidly recommend alternative courses of action that optimize deployment of medical treatment and evacuation assets, reduce support and maintenance requirements, and focus medical logistics support within the joint battlespace.

b. Improved Evacuation and Treatment is defined as the ability to use integrated networks of Global Positioning Systems, specialty-specific telementoring and teleconsultation, telerobotics, and advanced life support and transport systems to rapidly locate, diagnose, treat and evacuate casualties when time is the critical variable that will determine mortality and morbidity. This includes the development of techniques and clinically focused technology systems and linkages that enable rapid identification of high priority casualty treatment requirements, real time coordination of medical treatment (intervention) and evacuation, synchronization of handoffs between Joint Service echelons of care, and execution of time critical invasive medical therapies. A premium is placed on interventions that can be used within the battle area or as close to it as possible, before or during evacuation. This capability element also includes the transmission of multimedia medical data for physician and/or computer aided analysis, teleconsultation in real time or store and forward mode, medical image analysis, 3D image processing, pre-surgical planning, and distance specialty support systems.

4. Biotechnology: The Army is currently transforming into an Future Force Warrior that will be more responsive, deployable, agile, versatile, lethal, survivable, and sustainable than the current (legacy) force. Realization of the Future Force Warrior will require soldier- centered and engineered systems that provide revolutionary operational capabilities. Specifically, soldier- centered systems will need to enhance the health and performance of soldiers; engineered systems will need to improve force projection, force protection and situational dominance. Medical forces and assets will have to be efficient, effective and capable of supporting the full spectrum of military operations.

Given the above, there are several biotechnology areas that are important for the medical technology research community to exploit in order to achieve significant gains in combat support effectiveness en route to the Future Force Warrior. Specifically, prospective Army medical applications of biotechnology include:

- Data fusion and storage;
- Health monitoring;
- High-resolution imaging;
- Battlefield (chemical/biological) sensors;
- Sensor networks; and
- Soldier therapeutics.

By extension, there are five general areas where biotechnology development is needed:

- Sensors- assay analysis, detection methods (e.g. detector arrays);
- Electronics and Computing- biocomputing (e.g. biological models), bio-molecular hybrid devices;
- Materials- tissue engineering (e.g. self-replicating systems, cartilage repair and replacement), hybrid materials;
- Logistics- miniaturization of biological devices (e.g. Microelectrical Mechanical-based systems, nanotechnologies); and
- Therapeutics- genomics and proteonomics (e.g. data gathering, analysis, and management techniques).

Given the various possibilities across the five areas of development, the Army seeks to support research that identifies, develops, and demonstrates bioscience and engineering technologies that are relevant to the above- mentioned military medical applications in specific and Future Force Warrior operational capabilities in general.

5. Bioterrorism Training/Education: The 2001 episodes of Anthrax exposure demonstrated the need for well- prepared and trained "front line" military and civilian professionals, including medical and medical support personnel and "first responders." Therefore, there is a requirement to develop and implement Web- based, bio-terrorism medical response education and training programs for a diverse user audience with a differing knowledge base. The overarching objective is to create a distributed learning environment that permits the interoperability of bio-terrorism medical response learning tools and course content on a global scale. Tools - devices, systems, programs - and prototypes should be accessible, adaptable, interoperable and reusable. Additionally, tools and prototypes should address one or more of the following functional areas:

- Bio-terrorism self- assessment;
- Knowledge building;
- Acquisition of new skills;
- Maintenance and enhancement of existing skills;
- Targeted delivery of information, content and services based on specific user needs.

All tools and prototypes should take into account the ongoing development and implementation of specifications and guidelines, such as the Sharable Content Object Reference Model (SCORM).

G. SPECIAL PROGRAMS

The USAMRMC is frequently directed by Congress to manage funding of research programs with specific goals and end-points for health related issues relevant to military personnel, military dependents, veterans, and the health of the American public. These research programs are generally concerned with topics relating to health-care delivery; to detection, diagnosis, control or eradication of specified diseases, conditions, or syndromes; or to other initiatives relevant to health needs. Funding of these areas is dependent upon Congressional direction and availability of funds.

Evaluation and selection of proposals is based upon scientific merit, programmatic relevance and Congressional intent for awarded funds. Military relevance, collaborative efforts with DOD and/or VA scientists and clinicians or other priorities may be evaluation criteria or requirements.

Criteria and requirements for submission and evaluation of proposals may differ from those of other USAMRMC solicitation instruments, as well as other requirements stated in this BAA. Such differences will be noted in the specific BAA Supplement or solicitation instrument. For example, these special programs usually specify a submission closing date, and a specific submission process. Other areas where differences may apply are:

1. Submission of Pre-Proposals of one page or longer may be required,
2. Submission of Letters of Intent may be required,
3. Full Proposal submission requirements may be sent to applicant with invitation to submit full proposal,
4. Progress reporting requirements may differ and will be detailed in award document,
5. Points of contact for Principal Investigator (PI) inquiries may be identified,
6. Travel Cost guidelines may differ, and
7. PI notification of proposal receipt may differ.

You will find detailed information on proposal evaluation and selection in the following section titled Evaluation and Selection.

II. GENERAL INFORMATION

A. USAMRMC AWARDS

The USAMRMC executes its extramural research program through the award of contracts, assistance agreements (grants and cooperative agreements) and other transaction awards. **The type of instrument used to reflect the business relationship between the recipient and the Government will be a matter of negotiation prior to award.** USAMRMC supporting contracting office, USAMRAA, will process proposals selected for funding.

To protect the public interest, the Federal Government ensures the integrity of Federal programs by only conducting business with responsible recipients. The USAMRMC uses the Excluded Parties List System (EPLS) to exclude recipients ineligible to receive Federal awards. The EPLS is online at http://epls.arnet.gov/. (Reference DODGAR 25.110)

A recipient organization should meet certain minimum standards pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities and conformance with safety and environmental statutes and regulations (OMB Circulars at www.whitehouse.gov/omb/).

Investigators are cautioned that awards are made to organizations, not individuals. A principal investigator (PI) must submit a proposal through, and be employed by a university, college, nonprofit research institute, commercial firm or Government Agency in order to receive support. (Federally Funded Research and Development Centers are not eligible for awards in accordance with FAR 35.017). **Should the PI of a funded project leave the recipient institution, both the PI and institution must contact USAMRAA as soon as possible to discuss options for continued support of the research project. Every effort should be made to notify USAMRAA prior to the PI leaving the institution.**

Organizations located outside of the U.S. may submit in response to the BAA, however, it is the organizations' responsibility to ensure that the research staff is able to complete the work without intercession by the DoD for a J-1 Visa Waiver on behalf of a foreign national in the United States. **In addition, the Government will not provide funds to reimburse scientists from communist or terrorist countries.**

An organization must be registered in the Central Contractor Registration database, which requires annual updates, to receive an award under this BAA. You may register online at www.ccr.gov or by calling 1-800-841-4421, 616-961-5757, DSN 932-5757.

Support funds may be provided incrementally during the life of the award. Under cost-reimbursement type awards, payments are made in response to monthly vouchers or invoices submitted by the awardee. Under grants and cooperative agreements, advance payments are normally made periodically, in accordance with the negotiated payment schedule included in the award document.

B. CONFLICT OF INTEREST

There are certain post-employment restrictions on former federal officers and employees as defined in Section 207 of Title 14 United States Code and Federal Acquisition Regulation (FAR), Part 3.104-4(c). If a submitter believes a post-employment restriction or conflict of interest exists, the situation should be discussed with the USAMRMC legal staff (telephone 301-619-2065) prior to expending time and effort in preparation of a proposal.

C. DISCLOSURE OF INFORMATION OUTSIDE THE GOVERNMENT

Proposals will only be disclosed outside of the Government for the sole purpose of technical evaluation. The USAMRMC obtains a written agreement from the evaluators that information in the proposal will only be used for evaluation purposes and will not be further disclosed. Proposals for funded projects will be subject to public release under the Freedom of Information Act to the extent that they are incorporated into an award document; proposals that are not selected for funding will not be subject to public release.

D. GOVERNMENT OBLIGATION

Only a warranted Contracting/Grants Officer may obligate the Government to the expenditure of funds for awards under this BAA. The Government does not fund preparation of proposals or support research that is inferred from discussions with technical project officers.

E. INFORMATION SERVICE

Submitters may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 telephone: 703-605-6000 (www.ntis.gov) to acquire information of existing research to avoid duplication of scientific and engineering effort.

F. CONFERENCE OR SYMPOSIUM SUPPORT

The USAMRMC may provide financial support (if funds are available) for conferences or symposia that benefit the Command's research program. Email or postcard will acknowledge receipt of Conference or Symposium Support Request. The submitter should receive a decision letter within 30 - 60 days of submission. Instructions for submitting a Conference or Symposium Support Request can be found in Appendix 1.

G. PREPROPOSALS

PIs are strongly encouraged to explore USAMRMC interest by submitting a preliminary research proposal (preproposal). Preproposals may be submitted at any time describing a specific idea or project that pertains to any of the research areas of interest outlined in the BAA. Brochures or other descriptions of general organizational or individual capabilities will not be accepted as a preproposal. All preproposals will be assigned an identification number and an e-mail or postcard will acknowledge receipt of a preproposal. Usually, the PI should receive a decision letter or e-mail on the preproposal within 30-60 days of submission. Instructions for submitting a preproposal can be found in Appendix 2.

H. FULL PROPOSALS

Receipt of full proposals will be acknowledged by e-mail or postcard. The identification log number for the full proposal will be the same number used for the preproposal (if one was submitted). Proposals should be prepared according to the instructions under Proposal Preparation. Proposal forms (Appendices 3-11) should be completed and included as part of the submission package. Electronic and scanned signatures are acceptable. Full proposals may be submitted without protocols for human and animal use (Appendices 9 & 10). However, protocols with required institutional approvals must be submitted not later than 60 days after award to ensure continuation of payment. The contracting office may grant exceptions in situations where human and/or animal use are not expected to begin until after the first year of the research project. In such cases, a time frame for submission of the appropriate protocols should be established during discussions/negotiations, prior to award. The length of time and the level of funding requested should be consistent with the nature and complexity of the proposed research. Generally, research proposals are awarded for three years, and in no case should the period of performance exceed five years.

III. EVALUATION AND SELECTION

A. EVALUATION FACTORS

The USAMRMC scientists or outside experts will evaluate preproposals for scientific merit and programmatic/military relevance. PIs whose Preproposals meet preliminary qualifications may be invited to submit full proposals. Full proposals will be evaluated using a two-tier review process. USAMRMC scientists and/or outside experts will conduct the first tier, peer review. Peer reviewers evaluate proposals and assign scores based on the following factors (in descending order of importance):

1. Military and Program Relevance: Does the proposal clearly address a relevant and significant military-related problem that can be solved by research and development studies? Does the proposed research meet current USAMRMC program needs and goals?

2. Research Objectives: Are the stated objectives clear, valid and logical? Is the research innovative?

3. Scientific Excellence: Are the plans, methods, techniques and procedures feasible, clear, valid, adequately referenced, and state-of-the-art?

4. Impact: How are the results of this research expected to impact the intended beneficiaries? Is there a dual purpose for this research?

5. PI and Key Personnel Qualifications: Are the qualifications, capabilities and experience of the proposed PI and other key personnel sufficient to achieve the proposed objectives?

6. Facilities: Are the proposed facilities and equipment, or unique combinations of these, adequate for the proposed objectives?

7. Budget: Does the budget reflect the actual needs of the proposed work? Have the requests for personnel, equipment, supplies and travel been fully justified and are the costs reasonable?

The second tier of the review, the programmatic review, may be conducted by a team consisting of expert USAMRMC scientists, other Federal Agency Representatives, outside scientists with diverse expertise, clinicians, consumers, or combinations thereof. The programmatic review is primarily concerned with three criteria: peer review recommendations, programmatic priorities and portfolio balance. Other programmatic priorities that may be considered include:

1. Congressional guidance
2. Military mission, relevance, health, medicine, beneficiaries
3. DoD Priorities
4. VA Priorities
5. Collaborations with federal researchers

B. SELECTION

After the two-tiered evaluation, proposals recommended for funding may be prioritized. A prioritized listing of alternates may also be prepared when warranted. Subsequent awards depend upon the availability of funds and fulfillment of requirements and priorities determined to exist at the time of award. In some cases, funding priorities may change as certain scientific tasks are addressed and new mission assignments arise. Award is also dependent upon demonstration by the applicant that they have adequately addressed the following requirements:

1. Research involving Human Subjects/Anatomical Substances (if proposed),
2. Research involving Animals (if proposed),
3. Facility Safety Plan (FSP),
4. Certificate of Environmental Compliance, and
5. Representations for Assistance Agreements or Representations & Certification for a Contract, as appropriate.

IV. AWARD ADMINISTRATION

A. INFORMATION RELEASE

Award recipients are required to agree to the release of information pertaining to the research and development supported by the USAMRMC. Statement 1 shall be included in all such releases; Statements 2-6 shall be included if relevant to the research being conducted:

1. "This work was supported by the US Army Medical Research and Materiel Command under Award No. _____. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army."

2. In conducting research using humans and/or human anatomical substances, the investigator is required to include approvals, forms and descriptions as outlined in Appendix 9 of this announcement.

3. "In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture." Include required assurances, approvals, forms and descriptions as outlined in Appendix 10.

4. "In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules." (www.nih.gov)

5. "In the conduct of research involving hazardous organisms, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories." (www.cdc.gov/od/ohs/biosfty/biosfty.htm)

6. "Information" includes but is not limited to news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and symposia.

B. FREEDOM OF INFORMATION ACT REQUESTS

The Freedom of Information Act (FOIA) (5 USC 552) provides a statutory basis for public access to official Government records. "Records" are defined to include documentation received by the government in connection with the transaction of public business. Records must be made available to any person requesting them unless the records fall under one of nine exceptions to the Act. (www.aclu.org/library/foia.html)

When a FOIA request asks for information contained in a successful proposal that has been incorporated into an award document, the submitter will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by USAMRMC in making its final determination concerning which information is or is not releasable. If information requested is releasable, the submitter will be given notice of USAMRMC's intent to release and will be provided a reasonable opportunity to assert available action.

C. SITE VISITS

During the term of the award, the PI is encouraged to visit USAMRMC laboratories and institutes to discuss related work with USAMRMC scientists. All such visits must have prior funding and should be coordinated through the USAMRAA Contracting/Grants Officer. Funding for visits may be made available through the award instrument. The USAMRMC laboratory personnel, as well as other DoD personnel, are also encouraged to visit the PI during their award efforts. The visits must all be coordinated with the Contracting/Grants Officer and are intended for technical discussion and monitoring of progress of the funded project.

D. REPORTS

Reports are necessary for continuation of the research efforts and funding. Each award instrument will state the necessary reports that are due to the government. Reporting requirements may include the following:

1. Monthly or quarterly reports that outline the accomplishments and progress for that period.

2. Quarterly Standard Form Report, SF272, Federal Cash Transaction Report, used for grants and cooperative agreements, that track the expenditure of funds on the project.

3. Annual reports that consist of detailed summaries of scientific issues, accomplishments and animal research usage during the project.

4. Final report that details the findings and issues of the completed project.

5. Copies of all scientific publications as a result of funding.

6. Abstracts that are suitable for publication in relation to planned meetings.

7. Oral Presentations that detail the status of a project to a panel of subject matter experts.

8. Programmatic Meetings that include discussions regarding findings, accomplishments and direction for the program.

V. PROPOSAL PREPARATION

A. Formatting

Proposals must be submitted on one CD/DVD in PDF or Microsoft Office format. The CD/DVD must be labeled with the following contact information in case the disc is unreadable: organization's & PI's names, the e-mail address and phone number for a point-of-contact. Required forms, signed by the appropriate persons, must be included on the disc. Electronic signatures are acceptable or the signed forms can be scanned and included in the proposal. Submit the complete proposal, including the appendices on one disc. The proposal can be mailed or hand delivered to:

US Army Medical Research Acquisition Activity
ATTN: BAA 04-1
820 Chandler Street
Fort Detrick, MD 21702-5014

The proposal must be clear and legible, and conform to the following guidelines:

1. Type Font: 12 point, 10 pitch

2. Type Density: No more than 15 characters per inch (including spaces). (For proportional spacing, the average for any representative section of text should not exceed either 15 characters per inch or 114 characters per line.)

3. Spacing: Single-spaced between lines of text, no more than five lines of type within a vertical inch

4. Margins: Minimum of 0.5-inch top, bottom, right, and 1-inch left.

5. Color, Resolution and Multimedia Objects: Proposals may include color, high resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects must not exceed 15 seconds in length and a size of 10 megabytes (MB). Since some reviewers work from black and white printed copies, applicants may wish to include text in the proposal directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white. Photographs and illustrations, etc. must be submitted in JPEC format only (no bitmaps or TIFF).

6. Acronyms: Spell out all acronyms the first time they are used. One page following the proposal body is allocated to spell out acronyms, abbreviations and symbols.

7. Language: English

8. Print Area: 7.0 x 10.0 inches (approximately 18 cm x 25.5 cm)

B. COVER PAGE AND ABSTRACT.

Each proposal must include a completed Research Proposal Cover Page (Appendix 3) and Abstract (Appendix 4). These completed forms must be included with the proposal so that Cover Page and Abstract are foremost, as indicated in the Table of Contents (Appendix 5).

1. The Research Proposal Cover Page has been designed to request information that is not requested on other forms. A block for identifying the Area of Interest (i.e. Medical Biological Defense) or BAA Supplement (e.g. PRMRP, NETRP, TMM 04, etc.) has been added to facilitate processing proposals.

2. The abstract is vitally important to both the peer and programmatic review process. The programmatic review includes an evaluation of the abstract as part of the peer review summary statement; therefore, it is paramount that the investigator submits an abstract that fully describes the proposed work. The abstract must contain the title of the proposal and the name of the PI. Do not include figures or tables in the abstract. Spell out all Greek or other non-English letters. Abstracts of all funded proposals may be posted; therefore, proprietary or confidential information should not be included in the abstract.

The structured technical abstract should provide a clear and concise overview of the proposed work, including the background, objective, or hypothesis and its supporting rationale, significance of the proposed work to the program's goals, specific aims of the study and the study design.

An outline is provided below for preparing the structured technical abstract.

a. Background: Provide a brief statement of the ideas and reasoning behind the proposed work.

b. Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

c. Specific Aims: State concisely the specific aims of the study.

d. Study Design: Briefly describe the study design.

e. Relevance: Provide a brief statement explaining the potential relevance of the proposed work to the specific topic area being addressed and its impact on health outcomes.

A sample technical abstract can be found at www.usamraa.army.mil, under the BAA button.

C. PROPOSAL TABLE OF CONTENTS.

A table of contents (Appendix 5) should be included to show location of:

1. Research Proposal Cover Page
2. Abstract
3. Table of Contents
4. Statement of Work
5. Body of Proposal
6. Cost Estimate
7. Addenda

D. STATEMENT OF WORK

The Statement of Work (SOW) is the section of a research award that outlines and establishes the PI and an organization's performance expectations for which USAMRMC may provide support. Unlike the general objectives which are agreed to in a grant or cooperative agreement, the contract SOW sets rather specific goals and conditions for each year of the contracted project. The PI and contractor are expected to meet the provisions and milestones of the SOW. (The SOW may be incorporated into the award document and, as such, is subject to release under FOIA.)

A series of relatively short statements should be included which comprise the approach to each of the major goals or objectives of the proposed research. The statements should outline the specific tasks, systems and materials that are reasonable estimates for testing the proposed hypotheses of the study. An outline should be included which shows the work statements to be accomplished in each year of the award. The SOW for a three-year research effort should **not exceed one page** of single-spaced typing.

E. BODY OF PROPOSAL

A detailed description of the research to be undertaken should be submitted. This will include background, hypothesis, objectives, approach, methods, and their relationship to the state of knowledge in the field and to comparable work in progress elsewhere. This information should **not exceed 20 pages**. Evaluation of the proposed research will be influenced by the adequacy of this information. Literature references and curriculum vitae will be shown in separate addenda entries. The following general outline should be followed:

1. Background. Provide a brief statement of ideas and reasoning behind the proposed study. Describe previous experience most pertinent to this proposal. Cite relevant literature references;

2. Hypothesis. State the hypothesis to be tested and the expected results;

3. Technical Objectives. State concisely the question to be answered by each research objective;

4. Project Milestones: Identify time-lines for critical events that must be accomplished in order for the project to be successful in terms of cost, schedule and performance.

5. Military Significance. State precisely the estimates as to the immediate and/or long-range usefulness of this study to the Armed Forces, as distinguished from general advancement of knowledge in medicine.

6. Public Purpose. If appropriate, provide a concise, detailed description of how this research project will benefit the general public.

7. Methods. Give details about the experimental design and methodology. If the methodology is new or unusual, describe in sufficient detail for evaluation. For synthetic chemistry proposals include a clear statement of the rationale for the proposed syntheses. Outline and document the routes to the syntheses; and,

8. Investigator's Qualifications. By submitting a proposal and accepting an award, the organization is certifying that the investigator's credentials have been examined and verifying that the investigator is qualified to conduct the proposed study and to use humans or animals as research subjects, if proposed.

F. DETAILED COST ESTIMATE

An estimate of the total research project cost, with a breakdown of direct and indirect costs by category and year, must accompany each formal proposal (Appendix 6). All costs must be entered in U.S. dollars. Recipients performing outside of the U.S. should include the cost in local currency, the rate used for converting to U.S dollars and justification/basis for the conversion rate used. Multiple year proposals are encouraged to cover the total estimated duration of the project. Incremental funds may be provided by USAMRMC for effort performed during each Federal fiscal year. Costs proposed must conform to the following regulations and principles:

Commercial Firms: Federal Acquisition Regulations (FAR) Part 31 and Defense FAR Supplement Part 31, (http://farsite.hill.af.mil) Contract Cost Principles and Procedures.

Educational Institutions: OMB Circular A-21, Cost Principles for Educational Institutions.

Nonprofit Organizations: OMB Circular A-122, Cost Principles for Nonprofit Organizations. OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations.

State, Local and Tribal Governments: OMB Circular A-87, Cost Principles for State, Local and Indian Tribal Governments.

The cost of preparing proposals in response to this BAA is not considered an allowable direct charge to any resultant contract, grant or cooperative agreement. It is, however, an allowable expense to the bid and proposal indirect cost specified in FAR 31.205-18, and OMB Circulars A-21 and A-122. The following section provides instructions for preparing the Detailed Cost Estimate form. **Organizations must provide sufficient detail and justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research effort.**

1. Personnel:

a. Name: Starting with the PI, list the names of all participants who will be involved in the project during the proposed budget period, regardless of whether salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff.

b. Role on Project: Identify the role of each individual listed on the project. Describe his or her specific functions in the "Justification" section of the Detailed Cost Estimate form.

c. Type of Appointment (Months): List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The DOD staff assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time, e.g., 50%, note this with an asterisk (*) and provide a full explanation in the "Justification" section of the Detailed Cost Estimate form. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.

d. Annual Base Salary: Enter the annual institutional base salary for each individual listed for the project. The basis for labor costs should be predicated upon actual labor rates or salaries. Budget estimates may be adjusted upward to forecast salary or wage cost-of-living increases that will occur during the period-of-performance. The proposal should separately identify and explain the ratio applied to base salary/wage for cost-of-living adjustments and merit increases.

e. Percentage of Effort on Project: The qualifications of the PI and the amount of time that they and other professional personnel will devote to the research are important factors in selecting research proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on this project.

f. Salaries Requested: Enter the salaries in whole dollar figures for each position for which funds are requested. The salary requested is calculated by multiplying an individual's institutional base salary by the percentage of effort on the project.

g. Fringe Benefits: Fringe benefits may be requested in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant organization for all sponsors. Documentation to support the fringe benefits should be provided.

h. Totals: Calculate the totals for each position and enter these as subtotals in the columns indicated.

2. Consultant Costs: Regardless of whether funds are requested, provide the names and organizational affiliations of all consultants. State the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.

3. Major Equipment:

a. It is the policy of the DOD that all commercial and non-profit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and non-profit organizations, such approved cost elements shall be separately negotiated.

b. An itemized list of permanent equipment is required, showing the cost for each item. Permanent equipment is any article of nonexpendable tangible property having a useful life of more than two years and an acquisition cost of $5,000 or more per unit. The basis for the cost of each item of permanent equipment included in the budget must be disclosed.

(1) Vendor Quote: Show name of vendor and number of quotes received and justification if intended award is to other than the lowest bidder.

(2) Historical Cost: Identify vendor, date of purchase and whether or not cost represented lowest bid. Include release(s) for not soliciting current quotes.

(3) Estimate: Include rationale for estimate and reasons for not soliciting current quotes.

(4) Special test equipment to be fabricated by the contractor for specific research purposes and its cost.

(5) Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs, listing separately.

(6) Existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment those items of equipment that, if purchased by the contractor with contractor funds, would be capitalized for Federal income tax purposes.

(7) Title of equipment or other tangible property purchased with government funds may be vested in institutions of higher education or with nonprofit organizations, whose primary purpose is the conduct of scientific research. Normally the title will vest in the recipient if vesting will facilitate scientific research performed by the institution or organization for the Government.

(8) Commercial organizations are expected to possess the necessary plant and equipment to conduct the proposed research. Equipment purchases for commercial organizations will be supported only in exceptional circumstances.

4. Materials, Supplies and Consumables: A general description and total estimated cost of expendable equipment and supplies are required. Itemize supplies in separate categories (e.g., glassware, chemicals, radioisotopes). Categories in amounts less than $1,000 do not need to be itemized. If animals are to be purchased, state the species, strain (if applicable) and the number to be used. If human cell lines are to be purchased, state the source and the description.

5. Travel Costs: List the number of trips, number of people per trip, the destinations and the purpose for all proposed travel annually. Estimate round trip fare and per diem costs for each trip. Travel to scientific meetings requires identification of the specific meeting and purpose. Usually, no more than one trip to a scientific meeting for one person, usually the PI, is funded.

6. Research-Related Subject Costs: Itemize costs of subject participation in the research study. These costs are strictly limited to expenses specifically associated with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject's participation in the research study.

7. Other Expenses: Itemize other anticipated direct costs such as publication and report costs, rental for computers and other equipment (provide hours and rates), and communication costs. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints and distribution.

8. Subaward Costs: A description of services or materials that are to be awarded by subcontract or subgrant is required. The following information must be provided on subawards totaling $10,000 or more:

a. Identification of the type of award to be used (e.g., cost reimbursement, fixed price);

b. Identification of the proposed subcontractor or subgrantee, if known, and an explanation of why and how the subcontractor or subgrantee was selected or will be selected;

c. Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition; and

d. The proposed acquisition price.

e. The offeror's cost or price analysis for the subgrant or subcontract proposed price (applicable only if the award exceeds $500,000).

If the resultant award is a contract that exceeds $500,000 and the offeror is a large business or an educational institution (other than HBCU/MI), the contractor is required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.7. A mutually agreeable plan will be incorporated as part of the resultant contract.

9. Indirect Costs (overhead, general and administrative, and other): The most recent rates, dates of negotiation, base(s) and periods to which the rates apply should be disclosed along with a statement identifying whether the proposed rates are provisional or fixed. A copy of the negotiated rate agreement should be provided with the proposal. If negotiated forecast rates do not exist, provide sufficient detail regarding a determination that the costs

included in the forecast rate are allocable according to applicable FAR/DFARS or OMB Circular provisions (see above). Commercial firms can also visit http://www.dcaa.mil for additional information on establishing indirect rates. Disclosure should be sufficient to permit a full understanding of the content of the rate(s) and how it was established.

As a minimum, submission should identify:

a. All individual cost elements included in the forecast rate(s);

b. The basis used to prorate indirect expenses to cost pools, if any;

c. How the rate(s) was calculated; and

d. The distribution basis of the developed rate(s).

10. Total Costs for the Entire Proposed Period of Support (second page of the Detailed Cost Estimate form): Enter the totals under each budget category for all additional years of support requested and itemize these totals in the "Justification" section of the Detailed Cost Estimate form. Note with an asterisk (*) and explain any significant increases or decreases from the initial year budget. All amounts should be in U.S. dollars. Total costs for the entire proposed period of support should equal the amount entered on the Proposal Cover Page.

11. Fixed Fee: A profit or fixed fee is not allowable on grants or cooperative agreements. If a profit or fee is negotiated, the award will be a contract. Any fixed fee applied to the research project must be listed and a claimed Facilities Capital Cost of Money supported by **DD Form 1861** (is http://www.dior.whs.mil/icdhome/forms.htm) submitted with the full proposal.

12. Justification (third page of the Detailed Cost Estimate form): Clearly justify each item in the budget under the "Justification" section of the Detailed Cost Estimate form.

G. ADDENDA

Include items appropriate to the proposal. Incomplete proposals will significantly delay both the review and any subsequent actions in processing the award.

1. Acronyms and Symbol Definition. Provide a glossary of acronyms and symbols, which might not be familiar to reviewers who are not current in the proposal, and research area.

2. Bibliography. List the references in the order they appear in the proposal narrative. Use a reference format, which gives the title of the citation. Do not send or attach copies of articles in print.

3. Biographical Sketch. (Appendix 7) Provide a biographical sketch for key personnel involved with the project and limited to **three** pages.

a. Principal Investigator and senior investigators. The qualifications of the PI and other senior professional key personnel are important factors affecting the selection of research proposals. Contracts, grants and cooperative agreements may be terminated when the PI severs connections with the organization or is unable to continue active participation in the research.

b. Other Personnel. List the names, titles, and participation of other scientific and technical personnel who will be directly associated with the project.

4. Existing/Pending Support. List the title, time commitments, supporting agency and level of funding for all existing and pending research projects involving the PI and key personnel. Provide justification for USAMRMC support and interest where the projects overlap or parallel. In order to enable a proper determination of the offeror's past performance, either for use in a technical evaluation or for determination of the necessary level of preaward survey, it is requested that synopsis of awards be prepared on similar or related effort for the past three years, including:

a. Specifics on each award, including types and dates of performance,

b. The name and address of the Procuring Contracting/Grants Officer; and,

c. The negotiated price, and the final cost to the Government, with reasons for the variance.

5. Collaboration and Joint Sponsorship. Provide letter(s) supporting stated collaborative efforts, which are provided at no cost, and are necessary for the project's success. Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal. In the absence of agreements among sponsors for joint support, the proposal should be structured so that the research can be carried out without the resources of any other sponsor. If, however, it is desirable to request partial support from another agency, the proposed plan should be stated and the reasons documented. If the plan cannot be formulated at the time the proposal is submitted, information should be sent later as an addendum to the proposal. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship.

6. Facilities/Equipment Description. Describe the facilities available for performance of the proposed request and any additional facilities or equipment proposed for acquisition at no cost to USAMRMC. Indicate if Government-owned facility or equipment is proposed for use. Reference should be made to the original or present contract under which the facilities or equipment items are now accountable.

7. Certificate of Environmental Compliance. Information regarding environmental compliance must be provided with the full proposal (Appendix 8).

8. Research Involving Human Subjects and/or Anatomical Substances. The PI must address all pertinent issues relating to the use of human subjects in the proposed research. Include the required approvals, forms and information as outlined in Appendix 9, Research Involving Human Subjects and/or anatomical substances. Full proposals may be submitted without protocols for human use. **However, protocols and required institution approvals must be submitted not later than 60 days after award to ensure continuation of payments.** The contracting office may grant exceptions in situations where human use is not expected to occur until after the first year of the research project. In such cases, a time frame for submission of the appropriate protocols should be established during discussion/negotiations.

9. Research Involving Animals. The PI must address all pertinent issues relating to the use of animals in the proposed research. Include the required assurances, approvals, forms and description in the proposal addenda entitled "Research Involving Animals," as outlined in Appendix 10. (Research conducted under USAMRMC sponsorship that generates preclinical safety data intended to support a research or marketing permit for products regulated by the Food and Drug Administration will be in conformance with the Good Laboratory Practices.) Full proposals may be submitted without protocols for animal use. **However, protocols and required institution approvals must be submitted not later than 60 days after award to ensure continuation of**

payments. The contracting office may grant exceptions in situations where animal use is not expected to occur until after the first year of the research project. In such cases, a time frame for submission of the appropriate protocols should be established during discussion/negotiations.

10. Facility Safety Plan. The facility safety plan is outlined in Appendix 11 and must be addressed in the full proposal.

11. Assistance Package Certifications and Assurances, Assistance Package Representations or Representations & Certification for a Contract, as appropriate, must be submitted with the full proposal. The forms are located at www.usamraa.army.mil under the buttons for Assistance Agreements or Forms.

12. Multimedia Objects, Photographs, Illustrations, Graphs, etc. Proposals may include color, high resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects must not exceed 15 seconds in length and a size of 10 megabytes (MB). Since some reviewers work from black and white printed copies, applicants may wish to include text in the proposal directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white. Photographs and illustrations, graphs etc. must be submitted in Microsoft Office or JPEC format only (no bitmaps or TIFF).

13. Other. Include in this section, any other documentation not specified elsewhere, that supports the research proposed and could influence the evaluation and selection process.

H. REGULATIONS AND FORMS

1. Copies of the Federal Acquisition Regulation (FAR) and Defense FAR Supplement referenced in this BAA may be purchased from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 or located at website http://farsite.hill.af.mil.

2. Office of Management and Budget Circulars referenced in this BAA may be obtained from:

EOP Publication Office
New Executive Office Building
725 17th Street, NW, Room 2200
Washington DC 20503

Telephone: 202-395-7332
Website www.whitehouse.gov/omb/

3. The formats and forms in Appendices 3-11 of this BAA are interactive and may be completed electronically for inclusion on the CD or DVD. Other forms and references made within this BAA can be located on the web. If you need assistance, contact:

US Army Medical Research and Acquisition Activity
ATTN: BAA 04-1
820 Chandler Street
Fort Detrick MD 21702-5014
FAX: 301-619-6662 to Cheryl Miles

4. The contracting/grants office may contact offerors whose proposals are selected for funding for specific certifications and statements required by Federal statutes and regulations. Failure to include all required information and completed forms with submission of the full proposal could delay the award process.

5. Code of Federal Regulations can be found at http://www.gpoaccess.gov/cfr/.